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\*Admitted only in Maryland  
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June 25, 2007

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Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**Mail Stop: Amendment**

Re: U.S. Utility Patent Application  
Application No. 10/614,116; Filed: July 3, 2003  
For: **Ketone Ligands for Modulating the Expression of Exogenous Genes  
Via an Ecdysone Receptor Complex**  
Inventors: TICE *et al.*  
Our Ref: 2584.0020001/RWE/RAS

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement Under 37 C.F.R. § 1.97(b);
2. One (1) page of Form PTO/SB/08A citing ten (10) documents;
3. A copy of five (5) of the cited documents (FP1-FP5);
4. Three (3) pages of Form PTO/SB/08B citing twenty (20) documents; and
5. A copy of the twenty (20) cited documents (NPL1-NPL20).

The above-listed documents are filed electronically through EFS-Web.


In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents  
June 25, 2007  
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

  
Robert A. Schwartzman, Ph.D.  
Attorney for Applicants  
Registration No. 50,211

RAS/las  
Enclosures  
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

TICE *et al.*

Appl. No.: 10/614,116

Filed: July 3, 2003

For: **Ketone Ligands for Modulating  
the Expression of Exogenous  
Genes Via An Ecdysone Receptor  
Complex**

Confirmation No.: 3335

Art Unit: 1633

Examiner: Popa, Ileana

Atty. Docket: 2584.0020001/RWE/RAS

**Information Disclosure Statement  
Under 37 C.F.R. § 1.97(b)**

*Mail Stop Amendment*

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms, PTO/SB/08A and PTO/SB/08B, are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of documents **FP1** to **FP5** and **NPL1** to **NPL20** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents, **US1** to **US5**, cited on the attached IDS Form, PTO/SB/08A, are not submitted.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following discussion of the relevance of the non-English language documents, **FP1-FP4**, **NPL1** and **NPL15**, cited on Forms PTO/SB/08A and PTO/SB/08B:

**FP1**, WO 01/60783 A1, is in a foreign language. An English language abstract of document FP1 is provided on the face page of the document.

**FP2**, WO 02/051820 A1, is in a foreign language. An English language abstract of document FP2 is provided on the face page of the document.

**FP3**, WO 02/053543 A1, is in a foreign language. An English language abstract of document FP3 is provided on the face page of the document.

**FP4**, WO 02/059077 A1, is in a foreign language. An English language abstract of document FP4 is provided on the face page of the document.

**NPL1**, Aumann, R., and Heinen, H., "(C-Amino)ketenimine, 2-Imidazolin-5-one and  $\alpha$ -Aminosäureamide aus (Aminocarben)chromkomplexen und Isocyaniden," *Chem. Ber.* 122:1139-1145, VHC Verlagsgesellschaft mbH (1989), is in a foreign language. An English language abstract of document NPL1 is attached as document **NPL19**.

**NPL15**, Sidel, W and Nahm, H, "Über die Hydrierung von  $\alpha$ -Benzoyl-N-acylserin-benzylestern," *Chem. Ber.* 88:900-911 (1955), VHC Verlagsgesellschaft mbH (1955), is in a foreign language. An English language abstract of document NPL16 is attached as document **NPL20**.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. §1.114, filed herewith. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Robert A. Schwartzman, Ph.D.  
Attorney for Applicants  
Registration No. 50,211

Date: June 25, 2007

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Substitute for form 1449/PTO

*(Use as many sheets as necessary)*

Sheet	1	of	1
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<b>Application Number</b>	10/614,116
<b>Filing Date</b>	July 3, 2003
<b>First Named Inventor</b>	TICE, Colin M.
<b>Art Unit</b>	1633
<b>Examiner Name</b>	Popa, Ileana
<b>Attorney Docket Number</b>	2584.0020001/RWE/RAS

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
	FP1	WO 01/60783 A1	08/23/2001	Ishihara Sangyo Kaisha, Ltd.		Abs
	FP2	WO 02/051820 A1	07/04/2002	Ono Pharmaceutical Co., Ltd.		Abs
	FP3	WO 02/053543 A1	07/11/2002	Shionogi & Co., Ltd.		Abs
	FP4	WO 02/059077 A1	08/01/2002	Takeda Chemical Industries, Ltd.		Abs
	FP5	EP 0 405 537 B1	09/08/2004	Warner-Lambert Company LLC		

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Examiner Signature		Date Considered	
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Substitute for form 1449/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				Application Number	10/614,116
				Filing Date	July 3, 2003
				First Named Inventor	TICE, Colin M.
				Art Unit	1633
				Examiner Name	Popa, Ileana
Sheet	1	of	3	Attorney Docket Number	2584.0020001/RWE/RAS

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	NPL1	Aumann, R., and Heinen, H., "(C-Amino)ketenimine, 2-Imidazolin-5-one and $\alpha$ -Aminosäureamide aus (Aminocarben)chromkomplexen und Isocyaniden," <i>Chem. Ber.</i> 122:1139-1145, VHC Verlagsgesellschaft mbH (1989)	Abs
	NPL2	Awad, W.I., <i>et al.</i> , "Studies on 2-Phenyl-4-Arlydene-5-Oxazolones," <i>Tetrahedron</i> 20:891-896, Pergamon Press Ltd. (1964)	
	NPL3	Choong, I.C., <i>et al.</i> , "Identification of Potent and Selective Small-Molecule Inhibitors of Caspase-3 through the Use of Extended Tethering and Structure-Based Drug Design," <i>J. Med. Chem.</i> 45:5005-5022, American Chemical Society (November 2002)	
	NPL4	Él'kinson R.S. and Ereemeev, A.V., "Reactions of Azirines with Sulfur Nucleophiles. 4. Treatment of 2H-Azirine With Mercaptosubstituted Acids. Reactions of Aziridinyl Alkyl Sulfides With Carboxylic Acids and Acyl Chloride Derivatives," <i>Chem. Heterocycl. Compd.</i> 22:161-166, Plenum Publishing Corporation (1986)	
	NPL5	Goujon, J-Y., and Shipman, M., "Concise route to $\alpha$ -acylamino- $\beta$ -keto amides: application to the synthesis of a simplified azinomycin A analogue," <i>Tetrahedron Lett.</i> 43:9573-9576, Elsevier Science Ltd. (Dec 2002)	
	NPL6	Huebner, C.F., and Scholz, C.R., "The Synthesis of Cholramphenicol Analogs," <i>J. Am. Chem. Soc.</i> 73:2089-2094, American Chemical Society (1951)	
	NPL7	Lachicotte, R.J., <i>et al.</i> , "C-Acylation of Hippurate and Related Esters Utilizing Multiple Anion Intermediate and Ethyl 4-Aminobenzoate," <i>Synth. Commun.</i> 20:63-69, Marcel Dekker, Inc. (1990)	
	NPL8	Liu, J., <i>et al.</i> , "Improved syntheses of $\alpha$ -BOC-aminoketones from $\alpha$ -BOC-amino-Weinreb amides using a pre-deprotonation protocol," <i>Tetrahedron Lett.</i> 43:8223-8226, Elsevier Science Ltd. (Nov 2002)	
	NPL9	MacPherson, E.J. and Smith J.G., "Alkali metal adducts of benzophenone azine. I. The sodium and potassium adducts," <i>Can. J. Chem.</i> 48:1904-1914, NRC Research Press (1969)	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				Application Number	10/614,116
				Filing Date	July 3, 2003
				First Named Inventor	TICE, Colin M.
				Art Unit	1633
				Examiner Name	Popa, Ileana
Sheet	2	of	3	Attorney Docket Number	2584.0020001/RWE/RAS

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>
	NPL10	Mizuno, H., <i>et al.</i> , "Stereochemical Studies. V11: Thermal Rearrangement of $\alpha$ -Hydroxyimines to $\alpha$ -Aminoketones using optically Active Open Chain Compounds," <i>Chem. Pharm. Bull.</i> 71:227-246, Pharmaceutical Society of Japan (1971)	
	NPL11	Ooi, T., <i>et al.</i> , "Asymmetric Induction in the Neber Rearrangement of Simple Ketoxime Sulfonates under Phase-Transfer Conditions: Experimental Evidence for the Participation of an Anionic Pathway," <i>J. Am. Chem. Soc.</i> 124:7640-7641, American Chemical Society (June 2002)	
	NPL12	Pines, H.S., <i>et al.</i> , "3-Aryl-2-methylserines. I. A New Synthesis," <i>J. Org. Chem.</i> 33:1758-1761, American Chemical Society (1968)	
	NPL13	Pines, S.H., and Sletzing, M., "3-Aryl-2-Methylserines III. Synthesis via Alanine Azlactone," <i>Tetrahedron Lett.</i> 9:727-728, Pergamon Press (1969)	
	NPL14	Pines, S.H., <i>et al.</i> , "3-Aryl-2-methylserines. II. Inversions at Carbon 3," <i>J. Org. Chem.</i> 33:1762-1767, American Chemical Society (1968)	
	NPL15	Siedel, W and Nahm, H, "Über die Hydrierung von $\alpha$ -Benzoyl-N-acyl-serin-benzylestern," <i>Chem. Ber.</i> 88:900-911, VHC Verlagsgesellschaft mbH (1955)	Abs
	NPL16	Subramanyam, C., and Chang, S.P., "Solid-Phase synthesis of peptidyl $\alpha$ -keto heterocycles," <i>Tetrahedron Lett.</i> 43:6313-6315, Elsevier Science Ltd. (Sept 2002)	
	NPL17	Tamaru, Y., <i>et al.</i> , "Sulfinate As Cocatalyst 3: Palladium Catalyzed Dimerization of Butadiene with Acylamino Ketones," <i>Tetrahedron Lett.</i> 21:3791-3794, Pergamon Press Ltd. (1980)	
	NPL18	Van Der Meer, S., <i>et al.</i> , "Chloramphenicol Analogues I DL-2-Dichloroacetamido-1-(4-pyridyl)-1,3-propanediol," <i>Recl. Trav. Chim. Pays-Bas</i> 72:236-246, Société chimique neerlandaise (1953)	

Examiner Signature		Date Considered	
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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	NPL19	STNEasy Database, Accession No.1989:422724, English language abstract for Aumann, R., and Heinen, H., "(C-Amino)ketenimine, 2-Imidazolin-5-one and $\alpha$ -Aminosäureamide aus (Aminocarben)chromkomplexen und Isocyaniden," <i>Chem. Ber.</i> 122:1139-1145, VHC Verlagsgesellschaft mbH (1989)	
	NPL20	STN Easy Database, Accession No. 1956:40246, English language abstract for Sidel, W and Nahm, H, "Über die Hydrierung von $\alpha$ -Benzoyl-N-acyl-serin-benzylestern," <i>Chem. Ber.</i> 88:900-911, VHC Verlagsgesellschaft mbH (1955)	

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Examiner Signature		Date Considered	
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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